

K111337

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510(k) SUMMARY
(Per 21 CFR 807.92)

JAN 25 2012

General Company Information

Name: Tornier, Inc.
Contact: Howard Schrayner
Regulatory Affairs Consultant

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Date Prepared January 11, 2012

General Device Information

Product Name: Tornier® Collagen Coated BioFiber™ Scaffold

Classification: "Absorbable Surgical Mesh"
Product code: FTL - Class II

Predicate Devices

Tepha, Inc., Inc.	TephaFLEX™ Surgical Mesh [510(k) Number K070894]
Tornier, Inc.	Tornier® BioFiber™ Scaffold – (Surgical Mesh) [510(k) K102788 and K093799]
Sofradim Production (Covidien)	PREVADH™ Surgical Mesh [510(k) K073287]
Artimplant AB	Artelon® SportMesh™ Tissue Reinforcement Mesh [510(k) K071887]

Description

Tornier® Collagen Coated BioFiber™ Scaffold is a bi-layer, synthetic absorbable reinforced woven fabric made from poly(4-hydroxybutyrate) fibers. The construction permits the mesh to be cut into any desired shape or size without unraveling. The device is supplied sterile, for single-patient use for the reinforcement of soft tissue where weakness exists.

Intended Use (Indications)

Tornier® Collagen Coated BioFiber™ Scaffold is intended for use where temporary wound support is required to reinforce soft tissues where weakness exists or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

Tornier® Collagen Coated BioFiber™ Scaffold is also intended for reinforcement of soft tissues, in conjunction with sutures and/or suture anchors during tendon repair surgery; including the reinforcement of rotator cuff, patellar, Achilles, biceps and quadriceps tendons.

Tornier® Collagen Coated BioFiber™ Scaffold is not intended for use as a replacement for normal body structures or to provide the full mechanical strength to support the rotator cuff, patellar, Achilles, biceps, or quadriceps tendons. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to the bone, provide mechanical strength for the tendon repair.

Substantial Equivalence

The mesh structure of the Collagen Coated BioFiber™ Scaffold is the same material used to form the mesh used in the predicate TephaFLEX™ Surgical Mesh and both the material and mesh structure are the same as that of the predicate Tornier® BioFiber™ Scaffold. The use of the collagen coating as a component of the Collagen Coated BioFiber™ Scaffold is equivalent to the structure used for the predicate PREVADH™ Surgical Mesh and the predicate Artelon® SportMesh™ Tissue Reinforcement Mesh.

In support of the claim of substantial equivalence, Tornier has presented data regarding the physical and mechanical characteristics as outlined in the FDA "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh". In addition, Tornier has conducted studies of collagen purity, biocompatibility testing in accord with ISO 10993, a functionality study, a shelf-life study and a biodegradation study.

This submission supports the position that the Tornier® Collagen Coated BioFiber™ Scaffold is substantially equivalent to previously cleared devices, including those listed above. A number of predicate devices list the same range of clinical uses.

Conclusions

Tornier, Inc. believes that the information provided establishes that similar legally marketed devices have been used for the same clinical applications as the Tornier® Collagen Coated BioFiber™ Scaffold. The materials from which the Tornier device is fabricated have an established history of use, and the devices have been tested in accordance with applicable FDA guidelines.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

JAN 25 2012

Tornier, Inc.
% Mr. Howard Schrayner
7701 France Avenue South - Suite 600
Edina, Minnesota 55435

Re: K111337
Trade/Device Name: Tornier® Collagen Coated BioFiber Scaffold
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: January 11, 2012
Received: January 12, 2012

Dear Mr. Schrayner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

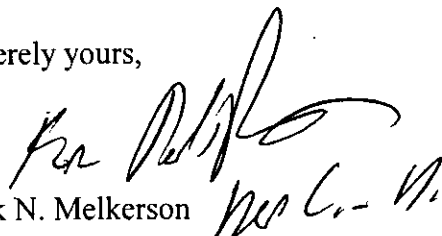
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K111337

Device Name: Tornier® Collagen Coated BioFiber Scaffold

Indications For Use:

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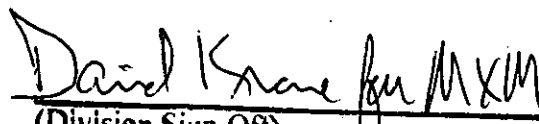
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111337